UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|--------------------|----------------------------|-----------------------|------------------|
| 10/554,021 | 10/21/2005 | Nicholas Michael Ian Noble | NL030483 | 7851 |
| 24737 7590 04/19/2007 PHILIPS INTELLECTUAL PROPERTY & STANDARDS P.O. BOX 3001 PRIABCLES MANOR NIV. 10510 | | | EXAMINER | |
| | | | BOR, HELENE CATHERINE | |
| BRIARCLIFF MANOR, NY 10510 | | ART UNIT | PAPER NUMBER | |
| | | | 3768 | |
| | | | | |
| SHORTENED STATUTORY | PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE | |
| 3 MON | ITHS | 04/19/2007 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | Application No. | Applicant(s) | | | | |
|--|---|--------------|--|--|--|--|
| Office Action Occurrence | 10/554,021 | NOBLE ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Helene Bor | 3768 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status . | | | | | | |
| 1) Responsive to communication(s) filed on 21 Oc | ctober 2005. | | | | | |
| ,— , | | | | | | |
| ; | ,—···································· | | | | | |
| | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>1-12</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-12</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | election requirement. | | | | | |
| Application Papers | | | | | | |
| | | | | | | |
| 9)⊠ The specification is objected to by the Examiner. 10)⊠ The drawing(s) filed on <u>21 October 2005</u> is/are: a)□ accepted or b)⊠ objected to by the Examiner. | | | | | | |
| <u> </u> | | | | | | |
| Applicant may not request that any objection to the | = : : | | | | | |
| Replacement drawing sheet(s) including the correcti | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | | |
| a) ☐ All b) ☑ Some * c) ☐ None of: | | | | | | |
| 1. ☐ Certified copies of the priority documents | s have been received. | | | | | |
| · · · · | | | | | | |
| | 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| • | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| P) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date Notice of Informal Patent Application | | | | | | |
| Paper No(s)/Mail Date 10/21/2005. | | | | | | |
| onk 10/21/05 | - - - | | | | | |

Application/Control Number: 10/554,021 Page 2

Art Unit: 3768

DETAILED ACTION

Acknowledgement of Preliminary Amendments

1. For the record, acknowledgement is made of the applicant's preliminary amendments to the claims under 37 CFR 1.115. It is acknowledged that applicant amended claims, 5-7, & 10. Under examination are the newly amended claims and the original claims, 1-12.

Acknowledgement of Information Disclosure Statement

 The information disclosure statement (IDS) submitted on 10/21/2005 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97.
 Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

Application/Control Number: 10/554,021 Page 3

Art Unit: 3768

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.

- (f) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- 4. The disclosure is objected to because of the following informalities:
 - a. Page 1, Line 10 "spatio"; --spatial--
 - b. Page 6, Line 13 "Fig. 4"; unclear --4a-- or --4b--

Appropriate correction is required.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 33. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

Application/Control Number: 10/554,021

Art Unit: 3768

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claim 1, 5 & 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Jolly'494 (US Patent Application No. 2003/0069494 A1).

Claim 1: Jolly'494 teaches a method of determining total left ventricular interior volume (Page 2, Para 0033) during a cardiac cycle from a cardiac cine series (Page 5, Para 0058). In addition, Jolly'494 teaches delineating endocardial and epicardial contours of a left ventricle in all slices of said cine series at end-diastole (ED) (Page 3, Para 0034 & 0040) and applying the endocardial contours delineated at ED to all phases of the cardiac cycle (Page 3, Para 0040). Jolly'494 teaches calculating the total LV interior volume based on intensity values inside the endocardial contours delineated at ED (Page 1, Para 0007, Page 2, Para 0033 & Page 4, Para 0042).

Claim 5/1: Jolly'494 teaches a method wherein the cine series is a short-axis study of the heart (Figure 2, Element a & c) consisting of multiple slices covering at least the left ventricle and multiple phases within the cardiac cycle (Page 5, Para 0058).

Application/Control Number: 10/554,021

Art Unit: 3768

Claim 7/1: Jolly'494 teaches a method wherein the cine series is/are captured previously to said method on a device for imaging inside parts of a mammal body (Page 1, Para 0004 & Page 5, Para 0058).

Claim 8/7/1: Jolly'494 teaches a method with a device for magnetic resonance imaging inside parts of a mammal body (Page 1, Para 0004).

Claim 9/8/7/1: Jolly'494 teaches a method wherein an MRI study comprises true Fast Imaging with Steady-State Precession (true FISP) also known in the art as Steady State Free Precession (SSFP) images (Page 5, Para 0058).

Claim 10/1: Jolly'494 teaches a method for compensating motion of the heart (Page 1, Para 0005 & Page 1 Para 0007 - 0011).

Claim 11: Jolly'494 teaches a using a suitable commercial cardiac analysis package and a computer platform with an operating system and micro instruction code. Jolly'494 teaches implementing the invention in various hardware, software or combinations thereof (Page 3, Para 0035). Jolly'494 teaches a computer program for calculating total left ventricular (LV) volume (Page 2, Para 0033) during a cardiac cycle from a cine series (Page 5, Para 0058). Jolly'494 teaches a computer program for delineating endocardial and epicardial contours of a left ventricle in all slices of said cine series at end-diastole (ED) (Page 3, Para 0034 & 0040). Jolly'494 teaches computer program for applying the endocardial contours delineated at ED to all phases of the cardiac cycle (Page 3, Para 0040), and the total LV volume based on intensity values inside the endocardial contours delineated at ED (Page 1, Para 0007, Page 2, Para 0033 & Page 4, Para 0042).

Art Unit: 3768

Claim 12/11: Jolly'494 teaches a computer program for automatically delineates the endocardial and epicardial contours (Page 3, Para 0040 & 0041).

Claim Rejections - 35 USC § 103

- 8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 10. Claim 2-4 & 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jolly'494 (US Patent Application No. 2003/0069494 A1) and further in view of Avinash'682 et al. (US Patent No. 6,980,682 B1).

Claim 2/1: Jolly'494 teaches using the intensity for performing calculations on the myocardium and blood voxels at ED based on the delineated endocardial and epicardial contours (Page 1, Para 0007, Page 2, Para 0033 & Page 4, Para 0042).

Jolly'494 fails to teach using the mean of the intensity for the calculations. However, Avinash'682 teaches using the mean of the intensity for the calculations (Col. 8, Line 8-24). It would have been obvious to one of ordinary skill in the art at the time the

Art Unit: 3768

invention was made to combine the teachings of Jolly'494 and Avinash'682 in order to produce greater accuracy and requires minimal user interaction (Col. 3, Line 35-40).

Claim 3/2/1: Jolly'494 teaches using intensities for the myocardium enclosed in the endocardial contours delineated at ED (Page 3, Para 0034 & 0040) during subsequent phases of the cardiac cycle (Page 3, Para 0040). Jolly'494 fails to teach using mean intensities. However, Avinash'682 using the mean intensities for compensating for myocardium enclosed in the endocardial contours (Col. 7, Line 1-18 & Col. 8, Line 8-24). It would have been obvious to one of ordinary skill in the art to combine the teachings of Jolly'494 and Avinash'682 in order to provide greater accuracy and requires minimal user interaction (Col. 3, Line 35-40).

Claim 4/3/2/1: Formulas and equations in the abstract are not patentable subject matter (MPEP 2106 Patent Subject Matter Eligibility). The following equation as claimed, is not taught by the cited references verbatim. However, Jolly'494 teaches calculating the LV interior volume is calculated (Page 2, Para 0033). Jolly'494 also teaches evaluating the total number of slices (Page 4, Para 0049) and the calculating interior volume of the LV at end-diastole (Page 3, Para 0034 & 0040). Jolly'494 teaches the detected intensity of the slice within the endocardial delimitation (Page 1, Para 0011) at ED (Page 3, Para 0040).

Claim 6/1: Jolly'494 teaches comprising determining the LV volume from cine sequences Jolly '494 fails to teach acquiring the images while the heart is under stress. However, Avinash'682 teaches evaluating the heart while under stress (Col. 1, Line 51-62). It would have been obvious to one of ordinary skill in the art to combine the

Application/Control Number: 10/554,021 Page 8

Art Unit: 3768

teachings of Jolly'494 and Avinash'682 in order to obverse abnormalities induced by stress (Col. 1, Line 56).

Conclusion

- 11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
 - a. Chenal et al. Acquisition Analysis and Display of Ultrasonic Diagnostic Cardiac Images, 13 June 2002. US Patent Application No. 2002/0072670 A1.
 - b. Cowan el al. Model Assisted Planning of Medical Imaging, 6 January
 2005. US Patent Application No. 2005/0004446 A1.
 - c. Criton et al. Strain Rate Analysis in Ultrasonic Diagnostic Images, 13 June2002. US Patent Application No. 2002/0072674 A1.
 - d. O'Donnell et al. Automatic Optimal View Determination for Cardiac
 Acquisitions, 10 February 2005. US Patent Application No. 2005/0033143 A1.
 - e. Paragios et al. Variational Approach for the Segmentation of the Left Ventricle in MR Cardiac Images, 18 July 2006. US Patent No. 7,079,674 B2.
 - f. Wei Li, MD et al. Dark Flow Artifacts with Steady-State Free Precession Cine MR Technique: Causes and Implications for Cardiac MR Imaging. Radiology 2004; 230:569-575.

http://radiology.rsnajnls.org/cgi/content/full/230/2/569.

The above reference cited was evidence to show in the art SSFP is also known as true FISP. The reference in the Introduction states, "Steady-state free precession (SSFP) imaging—also known by the acronyms FIESTA (fast imaging employing steady-state acquisition), true FISP (true fast imaging with steady-state precession), balanced FFE (fast field echo) and FRGRE (fully refocused gradient-recalled echo)—is increasingly being used in cardiac cine magnetic resonance (MR) imaging."

Art Unit: 3768

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947.

The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

Vendentell By 500 MONOTO MERIADER 808 3868